TRANSPYLORIC SHUTTLE/ TRANSPYLORIC SHUTTLE DELIVERY DEVICE INSTRUCTIONS FOR USE

RX ONLY

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

TPS Delivery Device Kit (Catalog No.: FG-0002) contents:

- One (1) TPS Delivery Device (w/ preloaded TPS implant)
- One (1) Advance Knob
- One (1) Introducer Sleeve
- One (1) 10cc Syringe
- One (1) Disposable Tubing Set (2 Tubes)
- Patient Implant Card
- Instructional Guides
    - TPS Deployment Preparation and Procedure Guide
    - TPS Troubleshooting - Incomplete Deployment (Checklist)

TransPyloric Shuttle

The TransPyloric Shuttle (TPS®) is constructed of four main components: the TPS external skin with weight assembly, the TPS coil, the lock lines, and the lock-release cap. These components are preloaded into the TPS Delivery Device. During the TPS delivery, the components are mechanically joined to construct the functional configuration of the TPS device. The components are secured by an internal-locking mechanism.

After being constructed, the TPS forms a smooth large bulb with a compliant tapered region (cone) connected to a small bulb by a flexible silicone tether (**Figure 1**). The dimensions of the device are shown in **Figure 2**.

The TPS is principally made of a medical-grade silicone elastomer and the TPS coil is loaded with barium sulfate for radiopacity. The external surface is coated with parylene.

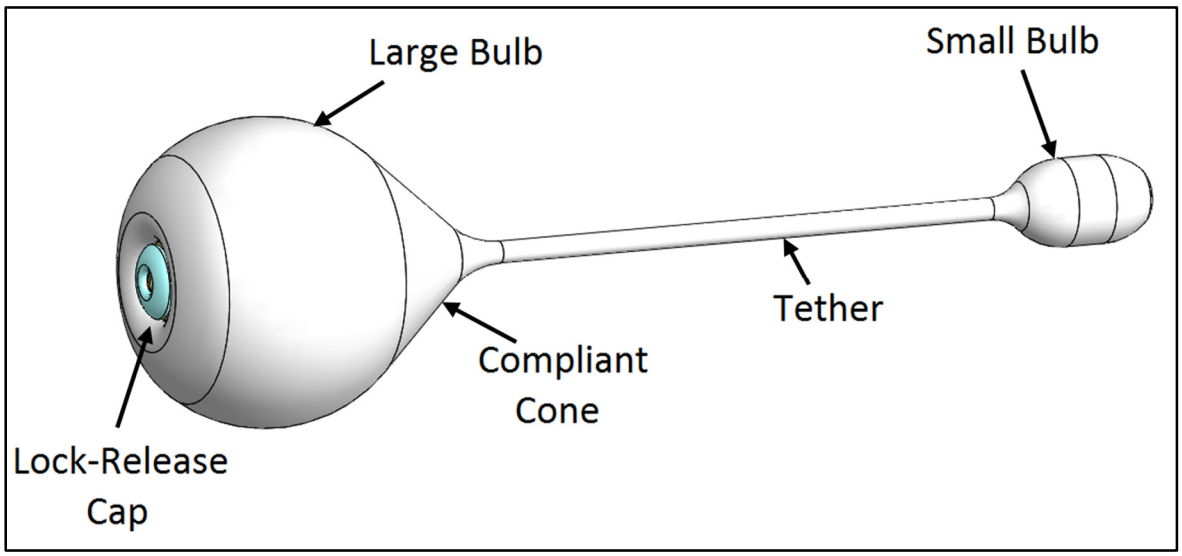

Figure 1. TransPyloric Shuttle

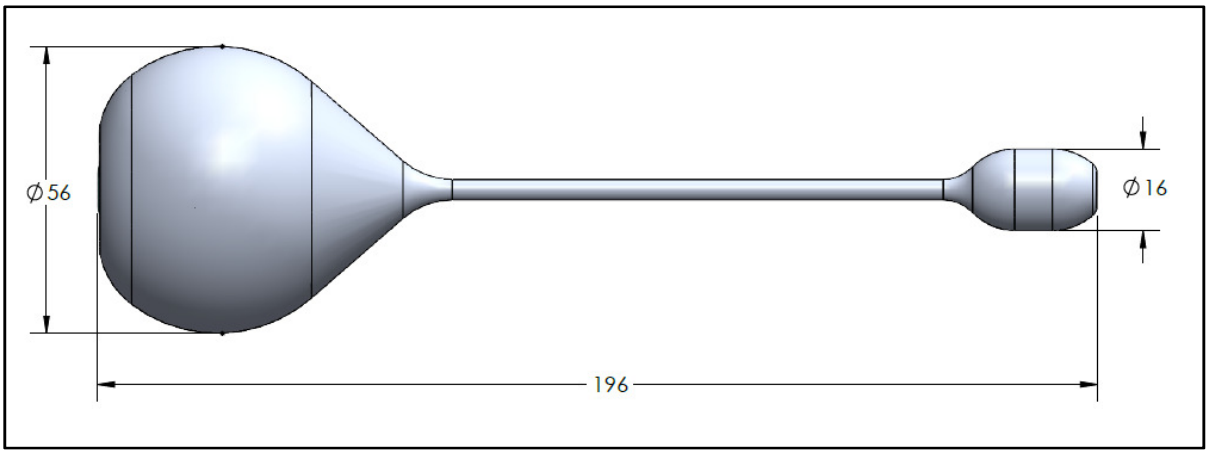

Figure 2. TransPyloric Shuttle Dimensions (mm)

TPS Delivery Device

The TPS Delivery Device is designed for trans-esophageal delivery of the TPS through the BARONova® Access Sheath. The Delivery Device consists of a distal PTFE shaft preloaded with TPS components, a proximal handle that controls the delivery mechanism, an outer slidable Introducer Sleeve that protects the TPS components during shaft introduction, and an Access Sheath connector that enables secure engagement with the proximal end of the Access Sheath for device positioning (**Figure 3**). An insufflation port allows for inflation of the TPS skin and insufflation of the gastric cavity during TPS delivery.

The handle on the Delivery Device provides the user interface for actuation of the delivery-system mechanisms that control deployment and release of the TPS. The Advance Knob limits the force that can be put into the system and the progress indicator provides visual feedback on the progress of the TPS coil deployment.

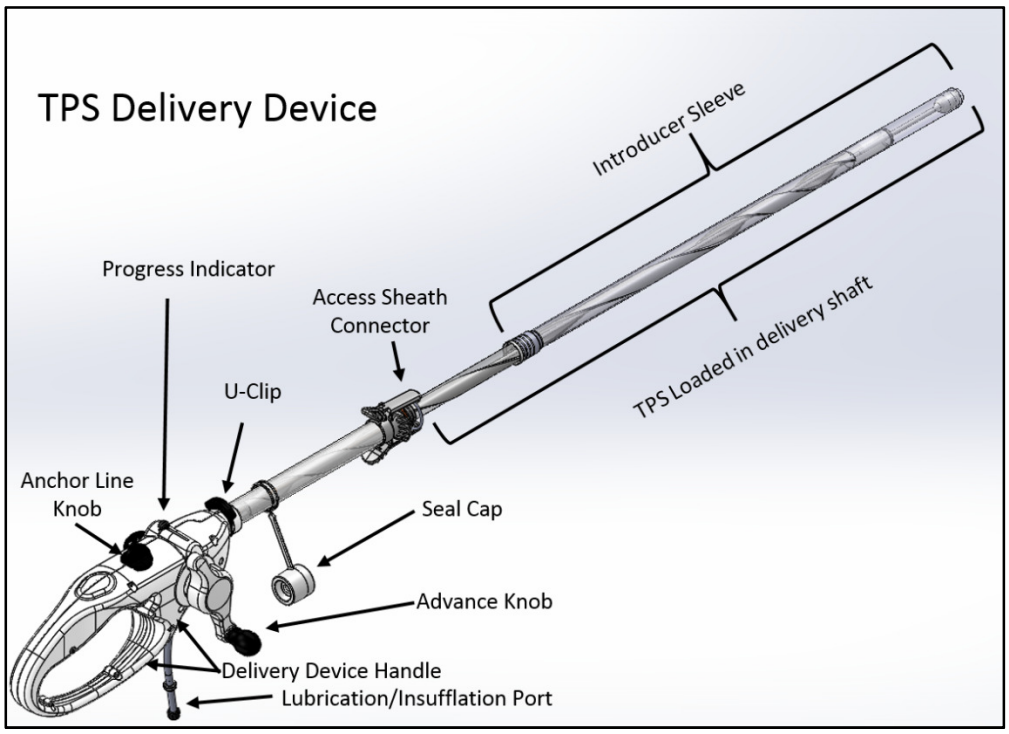

Figure 3. TPS Delivery Device

The TPS Delivery Device contains the following features:

- **Anchor Line Knob** – Removed after 3.5 deployment revolutions to extract Anchor Line.
- **Progress Indicator** – Moves from left to right to track deployment progress.
- **U-Clip** – Secures Device Handle to Delivery Tube/Shaft, removed to allow withdrawal of Handle from Shaft/Tube.
- **Access Sheath Connector –** Secures Delivery Device to Access Sheath after insertion.
- **Introducer Sleeve** – Applied during delivery device preparation to facilitate insertion into Access Sheath.
- **Advance Knob** – Torque-controlled crank rotated to drive TPS deployment and locking.
- **Delivery Device Handle** – White outer casing containing the Delivery Device drive system.
- **Lubrication/Insufflation Port** – Flexible tubing with ENFit connector port for internal device lubrication (prep) and insufflation (deployment)

INDICATION FOR USE

The TransPyloric Shuttle/TransPyloric Shuttle Delivery Device is indicated for weight reduction in adult patients with obesity with a Body Mass Index (BMI) of 35.0-40.0 kg/m^2 or a BMI of 30.0 to 34.9 kg/m^2 with one or more obesity-related comorbid conditions and is intended to be used in conjunction with a diet and behavior modification program.

CONTRAINDICATIONS

- Prior surgery or endoscopic intervention that has altered esophageal, gastric or duodenal anatomy.

- Structural abnormality in the esophagus or pharynx such as a stricture or diverticulum that could impede passage of an Overtube and/or an endoscope.
- Esophageal abnormality such as erosive esophagitis, eosinophilic esophagitis varices, telangiectasis, or other anomalies that could cause bleeding or other procedural complications.
- Patulous gastroesophageal junction.
- Known history of structural or functional disorders of the stomach including, gastroparesis, gastric ulcer, gastric mass, chronic gastritis, gastric varices, hiatal hernia (> 4cm), pyloric stricture, or any other disorder of the stomach.
- Inflammatory and other pathophysiological conditions of the GI tract, such as Crohn's disease.
- Untreated *Helicobacter pylori* infection.
- Active gastric or duodenal ulcers.
- Continuous therapy with known ulcerogenic medication (e.g., aspirin, NSAIDs).
- Coagulopathy or on anticoagulation or antiplatelet therapy.
- Unable or unwilling to take proton pump inhibitors (PPI), or addition of PPI may cause adverse drug interaction with subject's medication or interruption of treatment.
- History of portal hypertension, cirrhosis, and/or esophageal varices.
- Diagnosis of bulimia nervosa or binge eating disorder or other severe psychiatric disorders.
- Pregnancy or planned pregnancy in next 12 months.
- Known or suspected allergy to any component materials in the TPS such as silicone, barium sulfate, parylene.
- Any other medical condition that would not permit elective endoscopy or anesthesia such as poor general health or history and/or symptoms of severe renal, hepatic, cardiac, and/or pulmonary disease.

PRECAUTIONS

- It is the responsibility of the physician to advise the patient of known risks and complications associated with the procedure and the device.
- It is the responsibility of the physician to advise the patient of the potential need to remove the device in less than 12 months due to the development of refractory GI symptoms including, but not limited to nausea, vomiting, abdominal pain, or gastric outlet obstruction.
- It is the responsibility of the physician to advise the patient that the maximum placement period for the TPS is 12 months and it must be removed at that time or earlier. The safety and effectiveness of the device beyond 12 months is unknown.
- Patients should be counseled on the need for proper dietary and exercise habits. Failure to adhere to dietary and exercise instructions may result in failure to lose weight.
- Insertion and removal of the TPS should only be performed by physicians experienced in diagnostic and therapeutic endoscopy procedures and trained in performing TPS procedures.
- Prior to use, inspect the TPS Delivery Device and packaging. Do not use if open or damaged. In addition, do not attempt any modifications or repairs on the device. Use of open, damaged, or modified/repaired devices may lead to patient infection or impaired device performance and patient injury.
- The Delivery Device Kit components require generous lubrication with food-grade, oil-based lubricant, otherwise performance may be compromised.
- Do not use oil-based lubricant around flames or ignition sources as this may create a fire hazard.
- The TPS is composed of soft silicone. Care should be taken not to damage the TPS with endoscopic instruments.
- It is the responsibility of the physician to determine that the anatomy of the esophagus, stomach, pylorus, and duodenum is acceptable for TPS placement.

- The safety and effectiveness of the TPS device has not been established in patients with:
  - Type 1 diabetes or Type 2 diabetes requiring insulin
  - Cardiovascular disease such as recent acute coronary syndrome or clinically unstable ischemic cardiac disease.
  - History of pancreatitis
  - Alcohol or drug addiction
  - Altered mental status or cognitive impairment
  - Hormonal or genetic cause for obesity
  - Breast-feeding

WARNINGS

- Carefully review IFU prior to performing any procedure. **FAILURE TO FOLLOW PROCEDURE STEPS MAY RESULT IN SERIOUS PATIENT INJURY.**
- Insertion of medical devices or other equipment through the esophagus has the potential to cause serious patient injury – **NEVER FORCE DEVICES INTO PLACE DURING INSERTION PROCEDURES**.
- Physicians should consider the impact of slowed gastric emptying in patients taking medications on specified hourly intervals, such as anti-seizure or anti-arrhythmic medications.
- The risk of gastric outlet or intestinal obstruction may be higher in subjects who have had prior abdominal surgery or who have a dysmotility disorder or diabetes.
- The TPS Delivery Device Kit components are designed for single-use only. Attempts to re-process and/or reuse may lead to device failure and/or transmission of disease.
- Prophylactic Proton Pump Inhibitor (PPI) therapy is highly recommended. Patients failing to comply with required medical support may be at higher risk for esophagogastroduodenal tissue injury.
- Patients with obstructive symptoms including persistent nausea, vomiting, and/or abdominal pain, not responding to medical management, should be evaluated to rule out device impaction. In case of device impaction, the TPS device should be retrieved from the patient. Device impaction may recur if the TPS is repositioned.

POTENTIAL COMPLICATIONS

Any patient undergoing the TPS procedure is subject to unforeseen procedural and post-procedural risks (adverse events). Potential risks should be discussed with and understood by the patient prior to TPS placement. It is the responsibility of the physician to provide the patient with this information and to weigh the risk/benefit potential for each patient.

Each patient must be monitored during the entire term of treatment to detect the development of possible adverse events. Each patient should be instructed regarding symptoms of gastrointestinal obstruction, ulceration, and other adverse events which may occur, and should be advised to contact his/her physician immediately upon the onset of such symptoms.

Potential risks associated with an endoscopic procedure and anesthesia include, but are not limited to, adverse reaction to sedation (headache, muscle pain, nausea), anaphylaxis, cardiac arrest, death, hypoxia, infection, myocardial infarction, perforation, pneumonia, and respiratory distress.

Potential risks associated with the TPS include, but are not limited to:

- A feeling of heaviness in the abdomen.
- Abdominal cramps and discomfort from the air used to distend the stomach.
- Allergic reaction to the device's materials (e.g., silicone, barium sulfate and parylene).

- Alteration of the absorption rate of medications, particularly to enteric-coated medications. Influence on medication dosing, leading to the need to adjust dosing and potential associated complications if dosing is not adjusted, such as hypoglycemia, hypotension, etc.
- Aspiration of gastric contents, aspiration pneumonia.
- Biliopancreatic infection or obstruction, cholecystitis, pancreatitis.
- Cardiac or respiratory arrest during TPS procedures or endoscopy.
- Death.
- Esophageal trauma, perforation, and their related complications.
- Esophageal sphincter and/or pyloric sphincter incompetency associated with sphincter dilation during placement, residence or removal of the TPS.
- Excess reduction in oral intake, resulting in dehydration or malnutrition.
- Formation of intragastric bezoars.
- Gastroesophageal reflux.
- Gastric stasis and GI symptoms, such as abdominal pain, abdominal spasms, abdominal discomfort, nausea, vomiting, bloating, belching, dyspepsia, dysphagia, heartburn, halitosis, diarrhea or constipation.
- Gastroduodenal obstruction.
- Inability to endoscopically remove part or all of the TPS device, which may result in the need for surgery.
- Influence on digestion of food.
- Insufficient weight loss.
- Interference with abdominal imaging (e.g. CT, X-ray, ultrasound). For MRI, please refer to the MRI safety Information section below.
- Need for medication, endoscopic intervention, early TPS removal, or surgery to treat/correct complications.
- Oropharyngeal trauma, including bleeding, sore or irritated throat, inflammation or infection.
- TPS placement in an improper location such as in the esophagus or duodenum, which results in obstruction, bleeding, or perforation, and their related complications such as pneumothorax.
- Upper GI tract infection or bacterial overgrowth.
- Upper GI tract tissue injury or irritation, resulting in acute or chronic tissue inflammatory response, pain, bleeding, erosion, ulceration, strictures, stenosis, or perforation.

CLINICAL DATA

The ENDObesity II study was a multicenter, prospective, pivotal clinical study conducted at nine investigational centers in the United States. The study enrolled subjects into randomized and Open-Label cohorts. The randomized cohort was a double-blind, parallel sham-controlled study with 2:1 allocation to TPS and Control groups. A total of 270 subjects (181 TPS and 89 Control) were enrolled in this cohort. Upon completion of enrollment into the randomized cohort, 32 additional subjects were enrolled into an open-label cohort where all subjects were unblinded and received the TPS. All subjects in both cohorts received a low-intensity lifestyle counseling program.

Subjects were followed for 12 months or until study exit, whichever occurred earlier. This included in-clinic follow-up visits at 1 week and 1, 2, 4, 6, 9 and 12 months. Follow-up visits included physical exams, weight assessment, laboratory testing and patient-reported validated obesity-specific outcomes questionnaires. At each follow-up visit, subjects were provided with a brief, 15-minutes lifestyle modification education and counseling session. In addition, at months 7, 8, 10, and 11 a brief telephone contact was carried out to promote compliance.

Demographics

The baseline physical characteristics and demographics were similar between the TPS and the Control groups (**Table 1**).

Table 1. Baseline Characteristics

Parameter Mean (SD)	Randomized TPS (n=181)	Control (n=89)	Open-label TPS (n=32)
Age, Mean (SD)	43.0 (8.9)	43.9 (8.5)	41.9 (8.9)
Sex (female), N (%)	169 (93.4%)	83 (93.3%)	27 (84.4%)
Height (cm), Mean (SD)	165.8 (7.8)	164.7 (7.3)	165.6 (7.3)
Body Weight (kg), Mean (SD)	101.5 (11.9)	98.1 (10.9)	98.9 (12.4)
BMI (kg/m^2), Mean (SD)	36.8 (2.2)	36.1 (2.4)	36.0 (2.6)
Waist Circumference (cm), Mean (SD)	108.1 (9.7)	105.9 (8.5)	108.7 (10.7)
Ethnicity (Hispanic/Latino), N (%)	28 (15.5%)	12 (13.5%)	7 (21.9%)
Race, N (%)			
White	131 (72.4%)	65 (73.0%)	26 (81.3%)
Black/African American	32 (17.7%)	13 (14.6%)	5 (15.6%)
Asian	1 (0.6%)	0 (0.0%)	0 (0.0%)
American Indian/Alaska Native	1 (0.6%)	0 (0.0%)	0 (0.0%)
Native Hawaiian/Other Pacific Islander	1 (0.6%)	1 (1.1%)	0 (0.0%)
Hispanic or Latino	13 (7.2%)	6 (6.7%)	1 (3.1%)
Other	2 (1.1%)	4 (4.5%)	0 (0.0%)
Subjects with Comorbid Conditions, N (%)			
Diabetes	11 (6.1%)	5 (5.6%)	0 (0.0%)
Hypertension	46 (25.4%)	26 (29.2%)	14 (43.8%)
Hyperlipidemia	39 (21.6%)	21 (23.6%)	7 (21.9%)
≥ 1 Comorbid Conditions	117 (64.6%)	63 (70.8%)	20 (62.5%)
≥ 2 Comorbid Conditions	42 (23.2%)	20 (22.5%)	7 (21.9%)

Adverse Events

The endoscopic placement procedure for the TPS was attempted in 213 subjects (181 in the randomized cohort and 32 in the Open-Label cohort) and the TPS was successfully placed in 203 subjects (171 in the randomized cohort and 32 in the Open-Label cohort).

There were no deaths in the study. There were nine device- or procedure-related serious adverse events (SAEs) in six treated subjects (**Table 2**). Among them, seven SAEs in five subjects were related to TPS in residence, which resolved following endoscopic TPS removal, and one esophageal rupture that occurred during an unsuccessful delivery attempt and was associated with the development of a pneumothorax. The incidence of device- or procedure-related SAEs was 2.82% in all subjects in whom the TPS

deployment procedure was attempted (6/213, 95% C.I. 1.30%, 6.01%). Among subjects who received the TPS device, the most common SAE was device impaction that occurred in 1.97% (4/203).

Table 2. Device or Procedure-Related Serious Adverse Events

SAEs by MedDRA Categorization	# of Events	Subjects % (n/N)	Time to Onset (Days)	Device Removed Due to SAE
Esophageal rupture*	1	0.47% (1/213)	0	NA
Pneumothorax*	1	0.47% (1/213)	0	NA
Upper abdominal pain	1	0.49% (1/203)	2	Yes
Gastric ulcer**	1	0.49% (1/203)	119	Yes
Vomiting**	1	0.49% (1/203)	189	Yes
Device impaction **	4	1.97% (4/203)	Mean (SD): 195 (95) Range: 119-261	Yes

**Pneumothorax was due to the esophageal rupture, which occurred in the same subject.*
***Overlapping events. Device impaction included the patient with gastric ulcer (1) and the patient with vomiting (1).*

To improve TPS deployment success rate, a minor manufacturing modification was implemented during the study. After the modification, the TPS deployment success rate was increased to 99.1% (105/106) compared to a pre-modification success rate of 91.6% (98/107).

The following safety assessment was based on 203 subjects who received the TPS and 89 subjects in the Control Group (Safety Population) with the exception that the procedure-related adverse events assessment included all subjects in whom a TPS placement (213) or a sham procedure (89) was attempted (eITT population).

Table 3 summarizes device- and procedure-related adverse events. Almost all (99%) of TPS subjects had at least one device-related AEs during the study. The most commonly reported device-related adverse events were gastrointestinal events, most commonly nausea, upper abdominal pain, vomiting and dyspepsia, with the majority mild to moderate in severity. The incidence of procedure-related events was similar in both groups (63.9% vs. 62.9% in TPS and Control groups, respective); most commonly oropharyngeal pain associated with the procedure.

Table 3. Incidence and Severity* of Device and Procedure-Related Adverse Events

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Gastrointestinal Disorders									
Nausea	63.1%	mild moderate severe	30.1% 26.6% 6.4%	19.3%	mild moderate severe	10.8% 8.0% 0.5%	7.9%	mild moderate severe	5.6% 2.3% 0.0%
Abdominal Pain All**	70.0%	mild moderate severe	48.4% 42.2% 9.3%	18.9%	mild moderate severe	6.1% 12.2% 0.5%	11.2%	mild moderate severe	6.7% 5.6% 0.0%
Abdominal Pain Upper	62.6%	mild moderate severe	27.1% 27.1% 8.4%	14.1%	mild moderate severe	4.2% 9.4% 0.5%	11.2%	mild moderate severe	5.6% 5.6% 0.0%
Abdominal pain	7.9%	mild moderate severe	1.5% 5.9% 0.5%	2.8%	mild moderate severe	0.0% 2.8% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Abdominal pain lower	6.4%	mild moderate severe	3.0% 3.5% 0.0%	1.9%	mild moderate severe	1.9% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Vomiting	58.1%	mild moderate severe	22.2% 26.6% 9.4%	10.3%	mild moderate severe	3.8% 6.1% 0.5%	3.4%	mild moderate severe	2.3% 1.1% 0.0%
Dyspepsia	54.7%	mild moderate severe	24.6% 20.2% 9.9%	10.3%	mild moderate severe	7.0% 3.3% 0.0%	4.5%	mild moderate severe	3.4% 1.1% 0.0%
Diarrhea	37.9%	mild moderate severe	17.7% 13.3% 6.9%	1.9%	mild moderate severe	0.9% 0.9% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Abdominal distension	36.9%	mild moderate severe	25.1% 10.3% 1.5%	8.5%	mild moderate severe	7.0% 1.4% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Gastroesophageal reflux	34.5%	mild moderate severe	18.2% 12.3% 3.9%	3.8%	mild moderate severe	2.8% 0.9% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Eructation	33.0%	mild moderate severe	27.1% 5.9% 0.0%	5.6%	mild moderate severe	5.6% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Gastritis erosive	13.3%	mild moderate severe	10.8% 2.5% 0.0%	0.9%	mild moderate severe	0.9% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastric mucosa erythema	11.3%	mild moderate severe	8.4% 3.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastric ulcer	10.3%	mild moderate severe	4.4% 4.4% 1.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Constipation	7.4%	mild moderate severe	4.4% 3.0% 0.0%	2.4%	mild moderate severe	0.9% 1.4% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Abdominal pain lower	6.4%	mild moderate severe	3.0% 3.5% 0.0%	1.9%	mild moderate severe	1.9% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Dysphagia	3.9%	mild moderate severe	0.5% 3.5% 0.0%	0.9%	mild moderate severe	0.0% 0.9% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastritis	3.5%	mild moderate severe	3.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Flatulence	3.5%	mild moderate severe	1.5% 2.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Abdominal Discomfort	2.0%	mild moderate severe	0.5% 1.5% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Erosive duodenitis	2.0%	mild moderate severe	1.5% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Obstruction gastric	2.0%	mild moderate severe	0.0% 0.0% 2.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastric Polyps	1.5%	mild moderate severe	1.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Retching	1.0%	mild moderate severe	0.5% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Abdominal rigidity	1.0%	mild moderate severe	0.5% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Hematemesis	1.0%	mild moderate severe	1.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Esophagitis	1.0%	mild moderate severe	0.5% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Pylorus dilatation	1.0%	mild moderate severe	1.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Breath odor	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Coating in mouth	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Duodenal ulcer	0.5%	mild moderate severe	0.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Erosive esophagitis	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastric dilatation	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastric disorder	0.5%	mild moderate severe	0.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastrointestinal mucosal hyperemia	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastrointestinal mucosal disorder	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastrointestinal sounds abnormal	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Hematochezia	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Lip Swelling	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.4%	mild moderate severe	1.4% 0.0% 0.0%	2.3%	mild moderate severe	1.1% 1.1% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Gastrointestinal motility disorder	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Hypoesthesia oral	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Lip ulceration	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Mouth ulceration	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Oral disorder	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Respiratory, thoracic and mediastinal disorders									
Oropharyngeal pain	12.3%	mild moderate severe	8.4% 3.5% 0.5%	35.7%	mild moderate severe	27.2% 8.0% 0.5%	42.7%	mild moderate severe	38.2% 3.4% 1.1%
Cough	0.5%	mild moderate severe	0.0% 0.0% 0.5%	1.9%	mild moderate severe	1.4% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Pneumothorax	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.0% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Productive cough	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Injury, poisoning and procedural complications									

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Esophageal injury	6.4%	mild moderate severe	6.4% 0.0% 0.0%	9.4%	mild moderate severe	8.9% 0.5% 0.0%	9.0%	mild moderate severe	7.9% 1.1% 0.0%
Laceration	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Procedural nausea	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Procedural pain	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	4.5%	mild moderate severe	3.4% 1.1% 0.0%
Anesthetic complication	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Lip injury	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Skin abrasion	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
General disorders and administration site conditions									
Chest discomfort	1.0%	mild moderate severe	0.5% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Device intolerance	0.5%	mild moderate severe	0.0% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Device occlusion	0.5%	mild moderate severe	0.0% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Discomfort	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Fatigue	0.5%	mild moderate severe	0.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Non-cardiac chest pain	0.5%	mild moderate severe	0.0% 0.0% 0.5%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Polyp	0.5%	mild moderate severe	0.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Sensation of foreign body	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	4.5%	mild moderate severe	3.4% 1.1% 0.0%
Pain	0.0%	mild moderate severe	0.0% 0.0% 0.0%	3.8%	mild moderate severe	1.4% 1.9% 0.5%	2.3%	mild moderate severe	1.1% 1.1% 0.0%
Pyrexia	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Infusion site thrombosis	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Infections and Infestations									
Gastroenteritis	2.0%	mild moderate severe	1.5% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Gastroenteritis viral	2.0%	mild moderate severe	0.5% 1.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Small intestinal bacterial overgrowth	0.5%	mild moderate severe	0.0% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Viral upper respiratory tract infection	0.5%	mild moderate severe	0.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Upper respiratory tract infection	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.0% 0.5% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Metabolism and nutritional disorders									
Dehydration	2.5%	mild moderate severe	0.5% 1.0% 1.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Hypokalemia	1.0%	mild moderate severe	0.0% 1.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Hypocalcemia	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Musculoskeletal and connective tissue disorders									
Muscle spasms	1.5%	mild moderate severe	0.5% 1.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Back pain	1.0%	mild moderate severe	0.5% 0.0% 0.5%	0.5%	mild moderate severe	0.0% 0.5% 0.0%	2.3%	mild moderate severe	1.1% 1.1% 0.0%
Flank pain	0.5%	mild moderate severe	0.0% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Musculoskeletal pain	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	0.0% 1.1% 0.0%
Neck pain	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	0.0% 1.1% 0.0%
Nervous system disorders									
Headache	1.0%	mild moderate severe	0.5% 0.5% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Ageusia	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Dysguesia	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Presyncope	0.5%	mild moderate severe	0.0% 0.0% 0.5%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Ear and labyrinth disorders									
Motion sickness	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Investigations									
Granulocytes abnormal	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Monocyte count increased	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

System Organ Class/ MedDRA Preferred Term	Device-Related (Safety Population)			Procedure-Related (eITT Population)					
	TPS (n=203)			TPS (n=213)			Control (n=89)		
	% subjects	Maximum Severity*		% subjects	Maximum Severity*		% subjects	Maximum Severity*	
Neutrophil count increased	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
WBC count increased	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Vascular Disorders									
Hematoma	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Eye disorders									
Eye hemorrhage	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%	1.1%	mild moderate severe	1.1% 0.0% 0.0%
Eye irritation	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%
Skin and subcutaneous tissues									
Subcutaneous emphysema	0.0%	mild moderate severe	0.0% 0.0% 0.0%	0.5%	mild moderate severe	0.5% 0.0% 0.0%	0.0%	mild moderate severe	0.0% 0.0% 0.0%

*__Adverse Events Severity:__

a. **Mild:** Causes no limitation of usual activities, may or may not require treatment and resolves with no permanent consequence.
b. **Moderate:** Interferes temporarily and causes some limitation of usual activities and most often requires treatment.
c. **Severe:** Prevents or severely limits usual activities

**Adverse events are reported per MedDRA coding. Abdominal pain (All) is a combined category, which includes all patients with any reported abdominal pain

The commonly reported GI symptoms were rated as mild or moderate in severity 84 to 100% of the time. A summary of the severity and timing of the common GI symptoms is shown in **Table 4**. The onset times for these gastrointestinal symptoms were not symmetrically distributed. The median time to onset of these common GI symptoms was 1-2 months (15-74 days) with a median duration for all symptoms but eructation of 3-17 days. Mild eructation had a median duration of 73 days.

The median times to onset for endoscopically documented erythema, erosive gastritis, and ulcer were 70, 196 and 273 days, respectively. Time to documented resolution of these findings was dependent on endoscopic interval. In the case of ulcers, this endoscopic follow-up was prescribed to be after approximately two months of healing time, and the median time to resolution was 68 days.

Table 4. Summary of Onset and Duration of Device-Related GI Events occurring in ≥ 10% of TPS Subjects (Safety Population)

MedDRA Preferred Term	TPS Subjects (N=203)	# Events	Event Severity Rating			Days to Onset Median, Mean and Range		Median Duration (Days)	Subjects with Event Onset ≤ 3 Days n/N (%)
			Mild # Events (%)	Mod. # Events (%)	Severe # Events (%)				
Nausea	128 (63.1%)	243	133 (54.7%)	93 (38.3%)	17 (7.0%)	Median: Mean: Range:	29.0 82.8 0-355	3.0	89/128 (69.5%)
Abdominal pain upper	127 (62.6%)	221	112 (50.7%)	86 (38.9%)	23 (10.4%)	Median: Mean: Range:	17.0 66.2 0-349	5.0	88/127 (69.3%)
Vomiting	118 (58.1%)	252	138 (54.8%)	92 (36.5%)	22 (8.7%)	Median: Mean: Range:	74.0 105.1 0-376	2.0	54/118 (45.8%)
Dyspepsia	111 (54.7%)	174	83 (47.7%)	65 (37.4%)	26 (14.9%)	Median: Mean: Range:	15.5 59.5 0-363	13.0	67/111 (60.4%)
Diarrhea	77 (37.9%)	126	59 (46.8%)	47 (37.3%)	20 (15.9%)	Median: Mean: Range:	52.0 86.5 0-350	3.5	22/77 (28.6%)
Abdominal distension	75 (37.0%)	110	83 (75.5%)	23 (20.9%)	4 (3.6%)	Median: Mean: Range:	33.0 67.4 0-327	7.0	24/75 (32.0%)
Gastro-esophageal reflux	70 (34.5%)	97	56 (57.7%)	31 (32.0%)	10 (10.3%)	Median: Mean: Range:	42.0 82.6 0-363	12.0	25/70 (35.7%)
Eructation	67 (33.0%)	81	68 (84.0%)	13 (16.0%)	0 (0.0%)	Median: Mean: Range:	27.0 77.8 0-324	73.0	20/67 (29.9%)
Gastritis erosive	27 (13.3%)	36	30 (83.3%)	6 (16.7%)	0 (0.0%)	Median: Mean: Range:	196.0 231.8 46-398	147.5	1/27 (3.7%)
Gastric mucosa erythema	23 (11.3%)	26	20 (76.9%)	6 (23.1%)	0 (0.0%)	Median: Mean: Range:	70.0 130.4 46-356	138.0	0/23 (0.0%)
Gastric ulcer	21 (10.3%)	23	11 (47.8%)	9 (39.1%)	3 (13.0%)	Median: Mean: Range:	273.0 270.7 119-373	68.0	0/21 (0.0%)

Gastroduodenal ulcers were observed in 10.3% (21/203) of TPS subjects at a mean time of 271 days (range 121 to 374 days). A total of 25 ulcers were observed in the study, which were reported in 23

adverse events. There were no ulcer bleeding or perforation complications. Ulcers were asymptomatic or with symptoms overlapping with symptoms of delayed gastric emptying. The ulcers responded to medical management and healing was achieved in a mean time of 73 days (range 56-117 days) after TPS retrieval.

Table 5. Summary of Endoscopic Ulcer Observations

Ulcer Observations	TPS (n=203)
Subjects with ≥ 1 Ulcer, n (%)	21 (10.3%)
Days to Endoscopic Observation of Ulcer Mean (SD) (Range)	271.2 (83.8) (121, 374)
Ulcer Location, n/N (%)	
Pre-pyloric	13/25 (52%)
Antrum	7/25 (28%)
Pyloric Channel	3/25 (12%)
Gastric body	1/25 (4%)
Proximal Duodenum	1/25 (4%)

Esophageal mucosal injuries occurred in 30 subjects with a similar frequency in TPS and Control subjects; 9.9% (21/213) and 10.1% (9/89) respectively**,** related to the passage of the Access Sheath or Overtube, and to a lesser extent the endoscope.

Forty-six (46/203, 22.7%) subjects who received the TPS device exited the study and had their TPS retrieved prior to 12-month follow-up. Of these, 22/203 (10.8%) exited at or prior to 180 days and 24/203 (11.8%) exited after 180 days. Five of these subjects exited due to a device-related SAE, 1 due to an SAE unrelated to device, 24 due to non-serious adverse events and 16 due to other reasons not associated with adverse events (**Table 6)**. Overall, the adverse event associated early exit rate was 14.8% (30/203). Data collected on patients who exited the clinical study prior to 12 months was analyzed to evaluate the total body weight loss achieved by these patients. These data represent a small number of patients and should be considered observational in nature and for informational purposes only. The mean percent total body weight loss was 7.2% (95% C.I. 4.1% to 10.2%) for 22 subjects who exited the study prior to 6 months and 12.2% (95% C.I. 8.5% to 15.9%) for 24 subjects who exited between 6-12 months.

Table 6. Summary of Adverse Events Associated with TPS Residence Time < 12 Months

MedDRA Preferred Term	# of Subjects with SAE	# of Subjects with AE	TPS (N=203) N (%)
Abdominal discomfort	0	1	1 (0.5%)
Abdominal pain upper	1	5	6 (3.0%)
Device impaction	4*	3	7 (3.4%)
Diarrhea	0	1	1 (0.5%)
Dyspepsia	0	1	1 (0.5%)
Dysphagia	0	1	1 (0.5%)
Fatigue	0	1	1 (0.5%)
Gastric ulcer	1*	0	1 (0.5%)
Gastroenteritis	0	1	1 (0.5%)
Nausea	0	3	3 (1.5%)
Vomiting	1*	7	8 (3.9%)

MedDRA Preferred Term	# of Subjects with SAE	# of Subjects with AE	TPS (N=203) N (%)
Meningioma**	1	0	1 (1.5%)

** Overlapping events. Device impaction included the patient with gastric ulcer (1) and the patient with vomiting (1)*

***Unrelated to device or procedure.*

Co-primary Effectiveness Endpoints

The study had two co-primary effectiveness endpoints:

- Mean percent total body weight loss (%TBL) between the Treatment and the Control group at 12 months after the index procedure.
- The proportion of subjects in the Treatment group who achieve ≥ 5 %TBL at 12 months after the index procedure.

The study hypothesis for the first co-primary endpoint was that the TPS subjects would have superior %TBL compared to the Control group subjects at 12-month follow-up. The first co-primary endpoint was evaluated using mixed models on multiply imputed samples. If a one-sided p-value was < 0.025, the null hypothesis was rejected.

The study hypothesis for the second co-primary endpoint was that the proportion of subjects in the TPS group with ≥ 5% TBL ("responders") at 12-month follow-up would be at least 50%. The second co-primary endpoint was evaluated as a Wilson's midpoint estimate and its 95% confidence interval on multiply imputed samples.

The effectiveness endpoints were evaluated based on the Per-Protocol (PP) population defined as subjects who received the assigned treatment and did not have any major eligibility violations in the randomized cohort.

Both co-primary endpoints were met:

- The mean percent total body weight loss (% TBL) was 9.5% for the TPS Group compared to 2.8% in the Control Group ($p < 0.0001$). The TPS group had an average of 6.7% (95% C.I. 4.5 to 8.8) greater %TBL than the Control group (**Table 7**).

Table 7. %TBL at 12 Months – PP population

$\%TBL_{12M}$	TPS (N=168)	Control (N=89)	Difference TPS-Control	p-value
LS* Means (SE) 95% C.I.	9.5 (0.7) 8.2 to 10.8	2.8 (0.9) 1.1 to 4.5	6.7 (1.1) 4.5 to 8.8	< 0.0001

**Least Squares*

- At the 12-Month follow-up visit, the proportion of TPS subjects who achieved ≥ 5%TBL was 66.8% (95% CI: 59.3 to 74.3) (**Table 8**).

Table 8. Proportion of Subjects in the TPS Group Achieving ≥ 5%TBL

	TPS (n=168)	**p-value***
Proportion of subjects with ≥ 5% TBL at 12-Months 95% C.I.	66.8% 59.3 to 74.3	< 0.0001

** p-value for the hypothesis that the proportion is equal to 0.5.*

The percent total body weight loss for the TPS and the Control groups over time is shown in **Figure 4.** The TPS treatment resulted in continued weight loss throughout 12 months, with the maximum weight loss achieved at Month 12. In comparison, subjects in the Control Group lost the majority of the weight in the first two months after the index procedure. The weight loss between 2 and 6 months in the Control group was marginal. Between 6 and 12 months, the subjects in the Control group regained a portion of the lost weight.

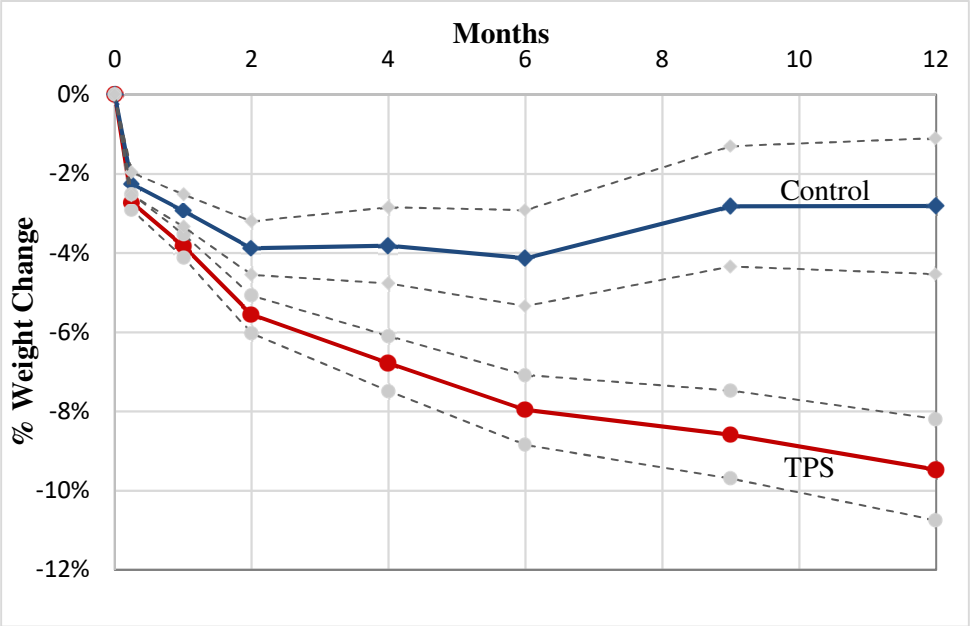

Figure 4. TPS and Control Group Weight Loss Over Time (PP Population)

Solid lines are mean % weight change, and the dotted lines represent the 95% confidence interval for the means.

Sensitivity Analyses

Sensitivity analyses were performed for co-primary endpoints using the Intent-to-Treat (ITT), Modified Intent-to-Treat (mITT), Completed Cases (CC) and other analysis populations as well as different imputation methods. All sensitivity analyses resulted in meeting the pre-determined statistical success criteria for effectiveness. The only exception was the worst-case scenario analysis using the back-to-baseline sensitivity approach for the second co-primary endpoint. The sensitivity analysis in the mITT population which included all subjects who were randomized and received the assigned treatment, is presented in **Table 9** and **Table 10**.

Table 9. %TBL at 12 Months (mITT Population)

$\%TBL_{12M}$	TPS (N=171)	Control (N=89)	Difference TPS-Control	p-value
LS Means (SE) 95% C.I.	9.3 (0.6) 8.1 to 10.6	2.8 (0.9) 1.1 to 4.5	6.5 (1.1) 4.4 to 8.7	< 0.0001

Table 10. Proportion of Subjects in the TPS Group Achieving ≥ 5%TBL (mITT Population)

	TPS (N= 171)	**p-value***
Proportion of subjects with ≥ 5% TBL at 12-Months **95% C.I.**	66.1% 58.7% to 73.5%	< 0.0001

Secondary Effectiveness Endpoints

Responder Rate

Responder rates for different threshold levels of weight loss are presented in **Table 11.** More than two-thirds of TPS subjects lost at least 5% total body weight compared to less than one-third of subjects in the Control Group. Approximately 40% of subjects in the TPS group achieved at least 10%TBL.

Table 11. Responder Rates at 12-Month Follow-up Visit by Group

	PP Population % subjects 95% C.I.		**mITT Population** % subjects 95% C.I.	
Parameter	**TPS (n=168)**	**Control (n=89)**	**TPS (n=171)**	**Control (n=89)**
≥ 5% TBL	**66.8%** 59.3% to 74.3%	**29.3%** 19.3% to 39.4%	**66.0%** 58.5% to 73.6%	**30.0%** 19.7% to 40.3%
≥ 7% TBL	**53.6%** 45.8% to 61.5%	**24.8%** 15.4% to 34.2%	**52.8%** 44.7% to 60.8%	**25.7%** 16.2% to 35.2%
≥ 10% TBL	**39.7%** 31.8% to 47.6%	**14.0%** 6.2% to 21.9%	**38.7%** 31.2% to 46.2%	**14.2%** 6.6% to 21.7%

Excess Weight Loss (EWL), Weight Loss, BMI and Obesity Class Changes

Table 12 summarizes percent excess weight loss, weight loss in pounds, BMI and obesity class changes. At the 12-Month follow-up, subjects in the TPS Group, on average, lost 30.9% of their excess body weight compared to 9.8% in the Control Group, with an observed difference of 21.1% EWL between the two groups. The mean weight loss was 21.1 lbs. (ranging from a weight loss of 81.2 lbs. to a weight gain of 8.1 lbs.) in the TPS group compared to 6.3 lbs. (ranging from a weight loss of 51.1 lbs. to a weight gain of 20.1 lbs.) in the Control group, with a difference of 14.8 lbs in favor of TPS treatment.
Subjects experienced decline in BMI that was greater in the TPS Group compared to the Control Group at all follow-up visits. At the 12-month follow-up visit, 52.4% (88/168) of subjects in the TPS Group achieved at least one Obesity Class reduction compared to 28.1% (25/89) in the Control Group, and

16.7% vs. 9.0% of subjects transitioned into non-obese BMI categories in the TPS and Control groups, respectively.

Table 12. Decrease in %EWL, Weight, BMI and Obesity Class at 12 Months

		PP Population			mITT Population		
		TPS (N=168)	**Control (N=89)**	**Difference TPS-Control**	**TPS (N=171)**	**Control (N=89)**	**Difference TPS-Control**
%EWL	LS Means (SE) 95% C.I.	**30.9 (2.2)** 26.6 to 35.3	**9.8 (3.0)** 3.9 to 15.6	**21.2 (3.7)** 13.9 to 28.4	**30.2 (2.2)** 25.8 to 34.6	**10.3 (3.0)** 4.4 to 16.2	**19.9 (3.7)** 12.5 to 27.2
Weight Loss (Ibs)	LS Means (SE) 95% C.I.	**21.1 (1.5)** 18.3 to 24.0	**6.3 (1.9)** 2.4 to 10.1	**14.8 (2.4)** 10.1 to 19.6	**20.5 (1.5)** 17.6 to 23.6	**6.3 (1.9)** 2.4 to 10.1	**13.9 (2.4)** 9.0 to 18.7
BMI Reduction (Kg/m2)	LS Means (SE) 95% C.I.	**3.5 (0.2)** 3.0 to 3.9	**1.0 (0.3)** 0.4 to 1.6	**2.5 (0.4)** 1.7 to 3.2	**3.4 (0.2)** 2.9 to 3.9)	**1.1 (0.3)** 0.5 to 1.7	**2.3 (0.4)** 1.5 to 3.1
Obesity Class Reduction	N (%) 95% C.I.	**88 (52.4%)** 44.8% to 60.0%	**25 (28.1%)** 18.8% to 37.4%	**24.3%** 12.3%-36.3%	**89 (52.1%)** 44.6% to 59.5%	**25 (28.1%)** 18.8% to 37.4%	**24.0%** 12.0% to 35.9%

Changes in Cardiometabolic Risk Factors, Quality of Life, and Eating Inventory

The changes in cardiometabolic risk factors, quality of life, and eating inventory from baseline to 12 months were predetermined secondary endpoints; however, no confirmatory statistical hypothesis testing was pre-defined with these endpoints.

Changes in blood pressure parameters in patients with baseline elevated blood pressure by group are shown in **Table 13;** changes in the total cholesterol, LDL and triglycerides in patients with a baseline hyperlipidemia (Total Cholesterol ≥200 mg/dL, LDL ≥ 130 mg/dL, Triglycerides ≥ 150 mg/d) by group are shown in **Table 14.**

Table 13 Changes in Blood Pressure at 12-Month in Subjects with Hypertension at Baseline (mITT Population)

		TPS	**Control**	**Difference TPS-Control**
DBP ≥ 80 mmHg at baseline	N	110	52	
	Baseline (Mean, SD)	86.9 (5.7)	87.6 (5.3)	
	12-Month LS Means Change (SE) 95% C.I.	**-5.4 (0.82)** -7.0 to -3.8	**-0.9 (1.2)** -3.3 to 1.4	**-4.5 (1.4)** -7.3 to -1.6
SBP ≥ 130 mmHg at baseline	N	90	46	
	Baseline (Mean, SD)	140.6 (7.8)	141.2 (8.0)	
	12-Month LS Mean Change (SE) 95% C.I.	**-8.2 (1.3)** -10.7 to -5.6	**-0.4 (1.8)** -4.0 to 3.2	**-7.8 (2.2)** -12.2 to -3.4

Table 14. Changes in Clinical Laboratory Values in Subjects with Elevated Baseline Values (mITT Population)

		TPS	Control	Difference TPS-Control
LDL ≥ 130 mg/dL at baseline	N	52	31	
	Baseline (Mean, SD)	152.7 (21.7)	154.3 (26.1)	
	12-Month LS Mean Change (SE) 95% C.I.	**-15.2 (3.7)** -22.7 to -7.7	**1.7 (4.9)** -8.0 to 11.3	**-16.7 (6.1)** -29.1 to -4.7
Total Cholesterol ≥ 200 mg/dL at baseline	N	68	42	
	Baseline (Mean, SD)	227.5 (30.2)	231.0 (32.7)	
	12-Month LS Mean Change (SE) 95% C.I.	**-13.6 (3.9)** -21.3 to -5.8	**-4.4 (4.9)** -14.1 to 5.3	**-9.2 (6.2)** -21.6 to 3.2
Triglycerides ≥ 130 mg/dL	N	51	26	
	Baseline (Mean, SD)	213.4 (54.6)	230.2 (109.7)	
	12-Month LS Mean Change (SE) 95% C.I.	**-47.2 (9.2)** -65.5 to -28.8	**-28.5 (13.2)** -54.9 to -2.2	**-18.6 (16.1)** -50.9 to 13.6

Quality of Life

Obesity-related quality of life outcomes as measured by IWQOL-Lite were also in favor of the TPS-treatment compared to Control in Total Score and Dimensions of Physical Function, Self-Esteem, Sexual Life and Work. The Public Distress outcomes were similar in both groups.

Eating Inventory

Eating Inventory was used to assess subject's eating behavior. At 12-Month follow-up, the TPS group performed better in Cognitive Restraint and Disinhibition than the Control group. Subjects in the TPS group also showed lower Hunger scores at 6 months.

HOW SUPPLIED

The TPS Delivery Device Kit (Catalog No. FG-0002) is supplied clean, non-sterile, and is packaged for single-use only.

The BARONova Access Sheath and BARONova Retrieval Kit (Catalog No. FG-0001) referred to in this IFU are supplied separately.

Any single-use device that is used in a partial or otherwise unsuccessful manner cannot be re-used on the same or different patient.

HANDLING AND STORAGE

Store in dry condition, away from temperature extremes.

PRE-USE INSTRUCTIONS:

Prior to clinical use, familiarize yourself with the device.

1. Verify "Use By" date.
2. Read the Instructions For Use and the Instructional Guides
3. Inspect the package. If damage is evident, do not use the device.
4. Ensure the OD of the gastroscope shaft and tip is compatible with the BARONova Access Sheath.

INSTRUCTION FOR USE

***Note: Deployment Preparation and Procedure Guide**, provided within the TPS Delivery Device Kit, may be used as supplemental information for preparation and operation of the device.*

TPS DELIVERY PROCEDURE

Required Devices and Materials

- TPS Delivery Device Kit (Model No. FG-0002)
- BARONova Access Sheath
- 30cc Syringe with Luer connector (for Access Sheath balloon inflation/deflation)
- Insufflation system – capable of providing pressurized air with controlled output pressure from 5 to 17 inH_2O (0.2 to 0.6 psi)
- BARONova Retrieval Kit (Model No. FG-0001) (if needed)
- Standard gastroscope, 9-11 mm OD, with single or dual working channels, with one working channel not less than 2.8 mm inside diameter with associated CCU, light source, and medical grade monitor
    - Not approved for use with side-viewing or tangentially viewing gastroscopes
- Mayo stand (adjustable height)
- Blunt/sharp point, open surgical scissors
- Bite block (minimum 60Fr)
- Lubricants
    - Water-based lubricant (e.g., K-Y Jelly®)
    - Food-grade spray lubricant (e.g., PAM®)
    - Food-grade liquid lubricant (e.g., PAM®)
- Reusable, flexible, endoscopic grasper (if needed)
    - 1 x 2 Rat Tooth – standard jaw, or elongated jaw

- Endoscopic polypectomy snares (if needed)
  - Crescent (1.5 cm – 2.5 cm), or Oval (1.5 cm x 3.0 cm)
- Hemostats (if needed)
  - 5 – 5.5 inch (straight or curved jaw)

Ensure that the patient has followed the recommended pre-procedure diet instructions so that no food or liquid is present in the stomach at the time of TPS procedure:

- Start liquid diet 36 hours prior to the procedure
- Start clear liquid 24 hours prior to the procedure
- Start NPO (nil per os) 12 hours prior to the procedure

Prepare patient for an upper GI endoscopic procedure. Anesthetize patient according to institution's standard procedure. Ensure adequate airway protection, as appropriate, during any TPS procedures. Place a minimum 60Fr bite block (e.g., OmniBloc® 60Fr).

Place patient in high left lateral recumbency:

- Right shoulder/hip approximating vertical and aligned
- Head/neck in neutral position

Perform standard diagnostic esophagogastroduodenoscopy (EGD) and inspect upper GI tract to rule out any conditions that may prevent the safe use of the TPS. If there is no contraindication,

- Prepare the insufflation system per manufacturer's instructions and check that output is set between 5 and 17 inH_2O (0.2-0.6psi) with the disposable tubing (provided in the TPS Delivery Device Kit) connected to the insufflation system.
- Prepare and insert the BAROnova Access Sheath according to the BAROnova Access Sheath Instruction for Use.

1. TPS Delivery Device Kit Preparation

1.1. Inspect primary TPS Delivery Device Kit packaging (**DO NOT USE IF OPEN OR DAMAGED**).

1.2. Remove system components from primary packaging. Set aside the Disposable Tubing Set for use with the insufflation system .

1.3. Remove and discard the orange plastic pin from the right side of the Delivery Device handle. Insert the Advance Knob (with the black knob facing towards the shaft of the Delivery Device). Fully seat the Advance Knob, allowing the black ring in the left side of the Delivery Device handle to slide out, and then re-seat fully in the handle.

1.4. TPS Delivery Device Lubrication

1.4.1. Fill 10 cc syringe with a minimum of 7cc food grade liquid oil lubricant.

1.4.2. Attach the lubricant-filled syringe to the connector on the Delivery Device insufflation port. Make sure the connection is secure and dispense the lubricant.

1.4.3. Hold the Delivery Device vertically (shaft down) and hold for ~30 seconds, until the lubricant reaches the distal end of the Delivery Device shaft.

1.4.4. Remove the emptied 10 cc syringe.

1.4.5. Remove the O-Ring and protective tube from the Delivery Device shaft. Do not displace the short clear tubing covering the distal end of the shaft.

1.4.6. Lubricate the inside of the short clear tubing at the end of the shaft with food grade spray lubricant (e.g., PAM®).

1.5. Introducer Sleeve Placement

1.5.1. Move Introducer Sleeve handle until it seats against the hard stop.

1.5.2. Thoroughly lubricate the inside of the Introducer Sleeve with food grade spray lubricant (e.g., PAM®).

1.5.3. Place the Introducer Sleeve handle on to the short clear tubing on the distal end of the Delivery Device shaft.

1.5.4. Grip at the Introducer Sleeve handle and support the delivery shaft above the short length of clear tubing. Advance the Introducer Sleeve ~2 inches at a time, and repeat until Introducer Sleeve is in final position, with the small bulb ~1/8" from the end of the Introducer Sleeve (with the tether straight). **DO NOT move the Introducer Sleeve** once it is in this position.

1.5.5. Leave the Introducer Sleeve in place and remove the Introducer Sleeve handle and short length of clear tubing by carefully advancing them distally over the Introducer Sleeve.

1.5.6. Lubricate the outer surface of the Introducer Sleeve (not the exposed delivery tube shaft).

2. Insertion of the Delivery Device

2.1. If desired, re-lubricate the outer surface of the Introducer Sleeve and/or the internal surface of the Access Sheath with the spray oil lubricant.

2.2. Note insertion depth of Access Sheath. With one hand securing the Access Sheath by the handle to prevent any forward advancement, slowly and carefully insert the Delivery Device shaft through the Access Sheath until the clips of the connector on the Delivery Device shaft positively engage into the handle of the Access Sheath. Applying light tension without twisting or excessive force to the Access Sheath can help maintain a low-force insertion. **DO NOT RETRACT THE DELIVERY DEVICE DURING INSERTION**.

2.2.1. If the Delivery Device is retracted after seating of the Introducer Sleeve handle into the Access Sheath, carefully remove Delivery Device and Introducer Sleeve (supporting the Introducer Sleeve and retracting it along with the rest of the Delivery Device).

2.2.2. Examine the Delivery Device and evaluate the position of the Introducer Sleeve on the Delivery Device shaft.

2.2.2.1. If the Introducer Sleeve has shifted position towards the Delivery Device handle to reveal the TPS small bulb and tether beyond the Introducer Sleeve, discard the Delivery Device.

2.2.2.2. If the Introducer Sleeve remains in the original position on the Delivery Device shaft, re-insert the Delivery Device into the Access Sheath, and continue the procedure.

3. Deployment of the TPS

3.1. If desired, place the device handle into a stand.

3.1.1. Inspect the insufflation tubing to ensure it is not kinked.

3.2. Position the Delivery Device handle at the same height as the patient's mouth. Minimize bending of the shaft and avoid acute insertion angles.

3.2.1. Take caution not to move the handle, and instead move the stand until the proper position is obtained.

3.2.2. Confirm proper insertion depth by verifying the depth marker on the Access Sheath as was established during Access Sheath placement. The Access Sheath's depth marker should be monitored throughout the procedure to confirm that the Access Sheath remains at the same insertion depth. **Failure to maintain the Access Sheath position after the balloon is inflated may result in pulling the balloon against the gastroesophageal junction resulting in serious tissue injury.**

3.3. Turn on the insufflation system and **verify that the output is between 5 in H_2O and 17 in H_2O with output tubing occluded**. Connect the insufflation system tubing to the Delivery Device insufflation port.

3.4. Begin deployment of the TPS by rotating the Advance Knob. Rotate in the direction of the arrow on the side of the Delivery Device handle. Proceed slowly and count Advance Knob revolutions. Stop at three and one half (3.5) full revolutions of the Advance Knob.

3.4.1. If the Advance Knob begins to click loudly and slip before 3.5 full revolutions are reached, perform step 3.5 (removing the black Anchor Line Knob), and continue the normal deployment procedure.

3.5. After 3.5 full revolutions of the Advance Knob, remove (pull upwards) the black Anchor Line Knob from the top of the handle. Continue to pull upwards until the free end of the anchor line is withdrawn from the handle, and then trim the exposed attached end near (within ~2 inches) the handle.

3.6. Resume rotation of the Advance Knob while monitoring the black Progress Indicator arrow advancement to the far right (~10 total revolutions, including initial 3.5 revolutions prior to anchor line removal).

3.6.1. If less than nine (9) full revolutions have been achieved and the Advance Knob is clicking and slipping, proceed to the **Troubleshooting - Incomplete Deployment Procedure** (below).

3.7. Continue rotation until the black Progress Indicator arrow reaches the end of its track (far right position), and the Advance Knob clicks and slips twice.

4. Locking of the TPS

4.1. Remove (pull out) the black ring from the left side of the Delivery Device handle.

4.1.1. If black ring resists removal, slowly rotate the Advance Knob while pulling on the black ring. Alternatively, first remove the Advance Knob, then remove the black ring. Return the Advance Knob to its position on the right side of the handle.

4.2. Rotate the Advance Knob slowly until it clicks twice.

4.3. Remove the Advance Knob and insert it on the left side of the handle. Rotate in the direction of the arrow on the side of the Delivery Device handle until it clicks twice, to confirm locking.

4.4. Return/re-insert the Advance Knob (right side of handle) and the black ring (left side of handle) to their original positions. Ensure the black ring is fully seated.

4.4.1. If the shaft of the black ring is not aligning with the Advance Knob, slowly rotate the Advance Knob until the parts align and seat.

5. Complete delivery and remove the Delivery Device.

5.1. Cut the four (4) white lines that are exposed in the slot of the hand-grip cutout.

5.2. Rotate the Advance Knob slowly at least 12 full revolutions to disengage the TPS from the Delivery Device.

5.3. Turn off the insufflation system, detach the tubing from the Delivery Device insufflation port, and set the insufflation system components aside for cleaning.

5.4. Remove the black U-Clip from the front of the handle by pulling it upwards.

5.5. Hold delivery tube in position and rotate Delivery Device handle one full turn **counter-clockwise** to resolve any residual torque in the system.

5.6. Support clear rigid tube immediately distal to the handle/U-Clip slot, while retracting Delivery Device handle. The Control Tube (small diameter tan tubing) and Plunger (white flexible rod) will be removed with the Delivery Device handle leaving the Delivery Device shaft and Access Sheath in patient.

5.6.1. If resistance is felt, toggle the handle rotationally (± 90 degrees) while retracting.

5.6.2. If high resistance persists after toggling the handle, disconnect delivery tube from Access Sheath (at the distal connector in Step 2.2), and retract delivery tube 1-2 inches to straighten tube and reduce resistance.

5.7. Discard the used Delivery Device.

6. Examine device and patient and remove Access Sheath and gastroscope.

6.1. Secure the clear Delivery Tube Seal Cap to the end of the remaining tube/sheath.

6.2. Insert gastroscope through the Delivery Tube Seal Cap to confirm the TPS has been properly formed. If TPS remains seated on the end of the delivery shaft/tube, the gastroscope may be advanced to push the TPS off of the tube to enable device inspection in stomach.

6.3. Inspect the formed TPS to confirm it constructed correctly (Lock-Release Cap not protruding, Coils even and spherically aligned, Skin covers Coil).

6.3.1. If TPS is malformed, complete Steps 6.4 through 6.5 and proceed to the **TPS Retrieval Procedure** (below).

6.4. **Under endoscopic visualization, fully deflate the balloon** of the Access Sheath using the 30 cc syringe, then detach the syringe.

6.5. Slowly withdraw the scope and Access Sheath together with the gastroscope trailing to allow visual assessment of the esophagus during removal. **DO NOT REMOVE ACCESS SHEATH WITH EXCESSIVE FORCE**.

6.6. Reinsert the gastroscope into the patient. Survey the gastric and esophageal tissues, then remove the gastroscope.

TROUBLESHOOTING - INCOMPLETE DEPLOYMENT PROCEDURE

Note: Troubleshooting – Incomplete Deployment (Checklist), provided within the TPS Delivery Device Kit, must be used to ensure proper execution of procedure.

1. Obtain scissors and reusable endoscopic rat-tooth grasper for troubleshooting procedure.
2. Access and cut all lines through the open Anchor Line Knob window (✚ shape) on the top of Delivery Device handle. A small hooked tool may be used to facilitate line access/engagement, if necessary.
3. Turn off the insufflation system, detach the tubing from the Delivery Device, and set the insufflation system components aside for cleaning.
4. Detach the Delivery Device by removing the black U-Clip. Hold clear rigid delivery tube in position and rotate Delivery Device handle one full turn **counter-clockwise** to resolve any residual torque in the system. Secure the delivery tube position by holding the rigid tube, and fully retract the Delivery Device handle from the delivery tube (carefully removing the small diameter tan tubing and white flexible rod) while leaving the delivery tube in place.
5. Lightly tension the exposed white lines and secure the clear Delivery Tube Seal Cap to the end of delivery tube (capturing the white lines) to enable insufflation to facilitate TPS removal.
6. Insert an endoscopic grasper into the gastroscope and insert the gastroscope into the delivery tube.
   6.1. If creases or kinks in the delivery tube path interfere with endoscopic maneuvers (gastroscope advancement/withdrawal, or TPS component removal), the operator may detach the connection between the delivery tube and the Access Sheath and retract the delivery tube approximately 1-2 inches to straighten delivery tube and reduce interference.
7. Use the grasper to remove the clear silicone dome. Unlock and remove the tan lock-release cap of the TPS (grasping and retracting the innermost ring) through the delivery tube. Detach the Delivery Tube Seal Cap to allow removal of the individual TPS components from the tube. Reattach the Delivery Tube Seal Cap to maintain insufflation during component removal.
8. Detach the Delivery Tube Seal Cap to free the white lines. Ensure the lock-release cap has been removed. Secure the rigid tube with one hand and remove white lines one at a time. There are four white lines looped through the TPS device, such that eight free ends will be accessible exiting the delivery tube. Withdrawal of a single line from the delivery tube will result in the other end of that line traveling into the delivery tube. Continue to pull each line individually until it is completely withdrawn from the delivery tube. Maintain control of all lines during removal to reduce potential for tangling or migration of the bundle of free ends into the tube. Repeat until all lines have been removed completely from the system.
   8.1. If the force required to remove a white line is felt to be excessively high, switch to pulling on a different white line or the opposing end of the line demonstrating resistance.
   8.2. Reattach the Delivery Tube Seal Cap after all white lines have been removed.
9. Insert the gastroscope to examine the position of the TPS Coil.
   9.1. If the TPS Coil is no longer inside the Access Sheath (i.e. partially inside the Skin, and released into the gastric space):

9.1.1. **Under endoscopic visualization, fully deflate the balloon** of the Access Sheath using the 30 cc syringe and detach the syringe.
9.1.2. Carefully withdraw gastroscope and delivery tube (w/Access Sheath) in unison to remove system from patient. **IF RESISTANCE IS FELT, CONFIRM THE ACCESS SHEATH BALLOON IS DEFLATED**.
9.1.3. Proceed to TPS Retrieval Procedure (next section, below) to complete TPS removal.
9.2. If the TPS Coil is still inside the Access Sheath continue to step 10.

10. Insert graspers into the gastroscope within the delivery tube. Ensure the white tension lines have been removed. Engage the proximal loop of the TPS coil with the graspers. Retract graspers and gastroscope together to withdraw and remove TPS coil through delivery tube.
10.1. During coil removal, stabilize/provide counterforce to the rigid tube to minimize the transfer of retraction force to the patient**.**
11. Reinsert gastroscope into delivery tube.
11.1. If the TPS Skin remains on the end of the delivery tube, push off with gastroscope. Note: Do not grab the TPS Skin at this time. **Deflate Access Sheath Balloon prior to retrieving the TPS Skin.**
12. **Under endoscopic visualization, fully deflate the balloon** of the Access Sheath using the 30 cc syringe and detach the syringe.
13. Use graspers or snares to engage the TPS skin tether approximately 1 inch away from the base of the small bulb.
14. Retract graspers/snare and gastroscope together to pull small bulb into delivery tube until mild resistance is felt (seating TPS skin at the end of the delivery tube).
15. Slowly withdraw gastroscope, graspers/snare, and delivery tube (w/Access Sheath) in unison to remove system from patient. **IF RESISTANCE IS FELT, CONFIRM THE ACCESS SHEATH BALLOON IS DEFLATED.**
16. Reinsert the gastroscope into the patient. Survey the gastric and esophageal tissues, then remove the gastroscope. Per physician discretion, re-initiation of the TPS deployment may be performed using another TPS Delivery Device (proceed to TPS Delivery Procedure step 1.1).

TPS RETRIEVAL PROCEDURE

Required Device and Materials

- BAROnova Retrieval Kit (Model No. FG-0001)
- Standard gastroscope, 8.8 – 11 mm shaft OD, 9.2 – 11 mm distal tip OD, with single or dual working channels, with one working channel not less than 2.8 mm inside diameter with associated CCU, light source, and medical grade monitor
  - Not approved for use with side-viewing or tangentially viewing gastroscopes
- Bite block (minimum 60Fr)
- Lubricants
  - Water-based lubricant (e.g., K-Y Jelly®)
  - Food-grade spray lubricant (e.g., PAM®)
- Reusable, flexible, endoscopic grasper
  - 1 x 2 Rat Tooth – standard jaw, or elongated jaw
- Endoscopic polypectomy snares
  - Crescent (1.5 cm – 2.5 cm), or Oval (1.5 cm x 3.0 cm)
- Hemostats (if needed)
  - 5 – 5.5 inch (straight or curved jaw)

Ensure that the patient has followed the recommended pre-procedure diet instructions so that no food or liquid is present in the stomach at the time of TPS removal procedure:

- Start liquid diet 36 hours prior to the procedure

- Start clear liquid 24 hours prior to the procedure
- Start NPO (nil per os) 12 hours prior to the procedure

Prepare patients for an upper GI endoscopic procedure. Anesthetize patient according to institution's standard procedure. Ensure adequate airway protection, as appropriate, during TPS retrieval procedures. Place a minimum 60 Fr bite block (e.g., OmniBloc® 60 Fr.). Place patient in lateral recumbency.

1. Prepare and insert the BAROnova Overtube contained within the BAROnova Retrieval Kit, according to its Instructions for Use and remove the Obturator.
2. Insert the gastroscope through the Seal Cap. Select and apply Endoscope Cap onto gastroscope per Retrieval Kit Instructions for Use.
3. Insert the gastroscope into the Overtube and install the Seal Cap onto the handle of the Overtube.
   3.1. Avoid withdrawing the gastrocopes with the Endoscope Cap installed through the Seal Cap. When removing TPS components, detach the Seal Cap to remove rather than retracting TPS components through the Seal Cap opening. Reinstall the Seal Cap after the component is removed.
4. Advance the gastroscope with Endoscope Cap through the Overtube and apply insufflation.
5. Optimize Overtube insertion depth (insert distal tip ~5 cm beyond gastroesophageal junction) to minimize tissue interference at Overtube tip in fully-insufflated stomach.
   5.1. Note insertion depth using external markers on Overtube shaft relative to bite block. Maintain target insertion depth established during Overtube placement throughout TPS retrieval procedure.
6. **TPS Unlocking**
   6.1. Locate proximal aspect of the TPS. Insert rat-tooth graspers and grasp the clear silicone dome of lock-release cap.
   6.2. Set the gastroscope in neutral position, and align the TPS axially with Overtube prior to retrieval of silicone dome cap.
   6.3. Manually secure the Overtube position, and with silicone dome engaged against the Endoscope Cap, retract gastroscope and grasper in unison, using the Overtube tip as counterforce against the TPS device as needed to remove the silicone dome.
   6.4. Withdraw gastroscope through Overtube and fully remove the silicone dome.
      6.4.1. If the lock-release cap is removed along with the silicone dome cap, skip to step 7.1.
   6.5. Re-insert gastroscope with Endoscope Cap, insufflating as needed, and locate the proximal face of the TPS.
   6.6. Insert rat-tooth graspers and grasp exposed innermost ring of the tan lock-release cap.
   6.7. Apply tension with grasper through endoscopic instrument channel to concentrically seat the TPS/lock-release cap firmly against the Endoscope Cap. Set the gastroscope in neutral position, and align the TPS in axial alignment with the Overtube prior to retrieval of lock-release cap.
   6.8. Manually secure the Overtube position, and with lock-release cap engaged against the Endoscope Cap, retract gastroscope and grasper in unison, using the Overtube tip as counterforce against the TPS device as needed to remove the lock-release cap.
      6.8.1. **Ensure no tissue is pinched between Overtube tip and TPS** and apply traction using the gastroscope and grasper together while manually securing the Overtube position to unlock the TPS. The inner ring of the lock-release cap should shift to protrude from the rest of the component (unlocked position).
   6.9. Withdraw gastroscope through Overtube and fully remove the lock-release cap.
7. **TPS Coil Removal**
   7.1. Re-insert gastroscope with Endoscope Cap in place, insufflating as needed.
   7.2. Locate the opening at proximal aspect of TPS where lock-release cap was removed.
   7.3. Insert snare and capture the tan TPS snare bead located within the proximal opening of the TPS.
      7.3.1. NOTE: Secure snare around distal groove of snare bead, away from silicone.
      7.3.2. If Snare Bead is not accessible, the white Suture Loop sewn into the rim of the coil may be engaged with graspers instead.

7.4. Apply tension with snare through endoscopic instrument channel to seat TPS snare bead firmly within the Endoscope Cap lumen, such that the base of the TPS snare bead is centralized within the Endoscope Cap.
7.5. Set the gastroscope in neutral position and align the TPS axially with the Overtube prior to retrieval of TPS coil.
7.6. Manually secure the Overtube position. Maintain secure engagement between TPS snare bead and Endoscope Cap, and retract gastroscope and snare, in unison, into the Overtube tip.
7.6.1. **Ensure no tissue is pinched between Overtube tip and TPS** and apply traction using the gastroscope and snare together, while manually securing the Overtube in position, to extract the proximal loop of the internal TPS coil from the external TPS skin. **DO NOT apply force without confirmation of tissue clearance.**
7.7. Continue to retract gastroscope and snare together to remove TPS coil fully from the Overtube.
7.7.1. When the TPS coil reached the Seal Cap, remove the Seal Cap and pull the TPS coil until approximately two inches of the coil are exposed beyond the Overtube handle. Manually secure proximal loop of the coil. Remove gastroscope and snare from device.
7.7.1.1. Proximal loop can be held with hemostats to prevent coil retraction.
7.7.2. Continue retrieval with manual retraction of coil, while securing Overtube in place to provide counterforce. Tactile feedback will inform user of separation of the internal coil from the external skin.
7.7.3. **If retrieval meets significant resistance prior to coil release**, two procedures are available to assist in releasing the internal coil from the external skin.
7.7.3.1. Overtube Reset: Release tension on coil (disengaging graspers/hemostats). Gently retract Overtube approximately 5-10 cm (the coil will retract deeper into Overtube). Do not use excessive force to retract Overtube: if resistance is felt, stop and proceed to 7.7.3.2. Slowly re-advance Overtube to original position, then re-grasp the coil and pull to remove. Repeat until coil release from skin has been achieved and remove coil fully through the Overtube. Return the Overtube to its original depth marker.
7.7.3.2. Push Tube Reset: Detach Seal Cap and disengage snare from TPS. Insert snare through Push Tube lumen until open loop extends beyond Push Tube. Snare TPS coil and advance open loop down length of coil with Push Tube, securing coil with gastroscope and graspers as necessary, until 10-15cm of externalized Push Tube remains. Close snare, release graspers from coil, and advance Push Tube, snare, and coil within Overtube to unseat from distal tip. Remove snare and Push Tube and resume coil retrieval.
7.7.3.2.1. Note: Do not retrieve coil by pulling on the Push Tube.

8. **TPS Skin Retrieval**
8.1. The Endoscope Cap may be removed from the gastroscope, if desired.
8.2. Re-install the Seal Cap onto the Overtube, and insert gastroscope, insufflating as needed.
8.3. Insert graspers or snare, and secure tether line of TPS skin approximately 1 inch away from the base of the small bulb.
8.4. Retrieve TPS skin until it is docked into the Overtube tip, and mild resistance is felt. The small bulb and tether should have advanced past the white Overtube tip, while the large bulb will be lightly tensioned against the distal end of the Overtube.
8.5. Fix gastroscope, graspers/snare, and Overtube together, and remove entire Overtube assembly in unison with TPS skin to complete the retrieval procedure. **DO NOT REMOVE OVERTUBE WITH EXCESSIVE FORCE**.
8.5.1. Dispose of the BARONOVA Retrieval Kit components according to its Instructions for Use.
8.6. Reinsert gastroscope to perform evaluation of gastric and esophageal tissues, then remove the gastroscope. Per physician discretion, re-initiation of the TPS deployment may be performed using another TPS Delivery Device (proceed to TPS Delivery Procedure step 1.1).

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the BARONova TransPyloric Shuttle (TPS) is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum MR system report, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the TPS is expected to produce a maximum temperature rise of less than 2.5 ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the TPS when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system.

TRAINING

A physician who performs the TPS placement and retrieval procedures should be experienced in diagnostic and therapeutic endoscopy procedures, and must have completed a physician-training program developed by BARONova.

PATIENT IMPLANT CARD

Implant Card is contained within the TPS Delivery Device Kit. Complete the information on the Implant Card and provide to the patient.

WARRANTY

BARONova expressly disclaims all warranties, whether written or oral, statutory, express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness or design. No other representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by BARONova for any purpose. BARONova neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

SYMBOL GLOSSARY

	Manufacturer (or manufactured for)
	Model/Catalog/Part Number (also known as Reference Number)
	Batch Code (also known as Lot number)
	Use-by date (YYYY-MM)
	Do not use if package is damaged
	Consult Instructions for Use
	Use only once
	Non-sterile
	Fragile
	Keep dry
	MR Conditional

MANUFACTURER

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This product and/or its use are covered by one or more of the following United States Patents: US6,994,095, US7,347,868, US8,048,169, US8,857,885 and US8,663,338. Other US patents pending. Foreign patents issued and pending.